EXHIBIT P

Revision History for dFMEA0000330, PROSIMA

Revision # (*Insert the Rev # in ascending order)*	**Summary of Change** *(Describe the change, and the section of the document where the change occurred.)*	**Change Order #** *(Insert the associated change order #)*	**Originator** *(Insert the author of the document or change)*
A	GYNECARE PROSIMA ORIGINAL RELEASE	N/A	D. Lamont
B	Updated Harms column to include Erosion as defined in RMR-0000029	N/A	D. Lamont

Design FMEA for Project MINT (PROSIMA)

Document No. FMEA-0000330 Rev. A

Project Name/Designation: PROSIMA

Scope: This Design FMEA covers the PROSIMA Pelvic Floor Repair System (PFRS) exclusive of packaging. For analysis purposes, all materials are considered sterilizable in the final packaging configuration. This dFMEA does not cover GYNEMESH PS properties or functionality (see reference documents).

Individuals providing input:	Initials	Department/Affiliation:	Title/Credentials:
Dan Lamont	DL	WWQE	DQE
Pete Komarnycky	PK	R&D	Engineer
Colin Harrier	CH	R&D	Engineer
Vincenza Zadem	VZ	R&D	Engineer
Dan Smith	DS	R&D	Project Lead (current)
Amith Kumar	AK	CPC	Engineer
Ronak Kadakia	RK	OPS	Engineer
Sunny Rha	SR	OPS	Engineer
Josh Samon	JS	R&D	Project Lead (former)
Kevin Gonzalez	KG	R&D	Engineer
Dave Robinson	DR	MA	Medical Director
Stephanie Kute	SK	R&D	Technical Lead
Bob Roda	BR	Marketing	Director
Jonathan Meek	JM	Marketing	Launch lead

Input Session(s):	Date:	Initials of Participants:
(1) VSD Failure modes	August 16, 2005	JS, VZ, PK, SR, DL
(2) All Functions	February 16, 2006	DL, VZ, CH
(3) Remaining Failure Modes	March 13, 2005	DL, VZ, AK
(4) Potential Causes	March 24, 2006	DL, AK, VZ, CH, RK
(5) PEs, Hazards, Harms	April 11, 2006	DL, CH, DS, VZ, RK, AK
(6) PEs, Hazards, Harms	May 19, 2006	DL, VZ, RK, DS, AK
(7) PEs, Hazards, Harms	August 2, 2006	DL, VZ, RK, AK
(8) Occurrence, Detection Rankings	September 29, 2006	DL, DR, DS, VZ
(9) Calculation of RPN, Risk Cats	October 6, 2006	DL
(10) Addition of Failure Mode(s)	January 22, 2007	DL
(11) General Format Update	March 8, 2007	DL
(12) Final Review	March 30, 2007	DL, DR, DS, BR, JM, AK
(13) Update -Add Erosion Harms	June 18, 2007	DL,DR

Document Owner for this Revision: Dan Lamont

Line ID	Component	Dwg # w/rev	Function	Potential Failure Mode	Potential Effect (PE)& Hazard (Haz)	Fault Class	Harm	Severity	Potential Cause	Occurrence	Basis	Control Method	Detection	RPN	Risk Category/ Further Action (after Options Analysis)
1	**Anterior Inserter**	**P21020**	Deliver mesh to tissue tunnels	Inserter length too long	PE: Control of inserter is reduced Haz: Inserter is driven further into target tissue than intended	**S**	Bowel/Bladder Erosion	**10**	Geometry, Population data	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**6**	**240**	RC: ALARP FA: None
2	**Anterior Inserter**	**P21020**	Deliver mesh to tissue tunnels	Inserter has incorrect curvature	PE: Inserter elongates tissue tunnel Haz: Inserter is placed too deep	**C**	Bowel/Bladder Erosion	**10**	Geometry, Population data	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing, Design Validation	**6**	**240**	RC: ALARP FA: None
3	**Mesh**	**P21005**	Provide lateral & Apical vaginal support	Incorrect body shapes	PE: Implant excessively large creating bunches and improper support Haz: Loss of Vaginal Support	**S**	Bowel/Bladder Erosion	**10**	Incorrect patient population data	**4**	D/A	Cadaveric User Evaluations, Dr. Carey's Study, DRM Memo-Mesh Size	**6**	**240**	RC: ALARP FA: None
4	**PROSIMA PFRS**	**PROA1, PROP1, PROC2**	Maintain device sterility until use	Device not sterile	PE: Packaging failed during transportation Haz: Product non-sterile	**S**	Infection	**10**	Damaged during transportation	**4**	T/E	Package/Ship Testing	**6**	**216**	RC: ALARP FA: None
5	**PROSIMA PFRS**	**PROA1, PROP1, PROC2**	Maintain device sterility until use	Device not sterile	PE: Incorrect or partial sterilization cycle Haz: Product non-sterile	**C**	Infection	**10**	Inadequate sterilization cycle	**4**	T/E	Sterilization Summary	**6**	**216**	RC: ALARP FA: None
6	**PROSIMA PFRS**	**PROA1, PROP1, PROC2**	Identify device and components	Labeling Information is Inadequate	PE: Out of sequence use of products, product damaged Haz: Extended Surgery	**S**	Extended Surgery	**9**	Lack of Information / Incorrect Information	**4**	T/E	Design Validation	**6**	**216**	RC: ALARP FA: None
7	**PROSIMA PFRS**	**PROA1, PROP1, PROC2**	Identify device and components	Expired Product is Used	PE: Degraded device / package performance Haz: Product non-sterile	**S**	Infection	**10**	Expiry Date is Hard to Locate	**4**	T/E	Design Validation	**6**	**216**	RC: ALARP FA: None
8	**PROSIMA PFRS**	**PROA1, PROP1, PROC2**	Maintain device functionality	Device is not functional when removed from package	PE: Non-functional device - Packaging failed during transportation Haz: None Identified	**S**	N/A	**8**	Damaged during transportation	**4**	T/E	Package/Ship Testing	**6**	**192**	RC: ALARP FA: None

Design FMEA: PROSIMA

Doc # 0000330

Line ID	Component	Dwg # w/rev	Function	Potential Failure Mode	Potential Effect (PE)& Hazard (Haz)	Fault Class	Harm	Severity	Potential Cause	Occurrence	Basis	Control Method	Detection	RPN	Risk Category/ Further Action (after Options Analysis)
9	**PROSIMA PFRS**	**PROA1, PROP1, PROC2**	Ease-of use by non-specialists	Difficult for inexperienced users to perform procedure	PE: IFU lacks clarity Haz: Increased complication rate for inexperienced users	**S,C,M**	Recurrence	**10**	Lack of clarity in IFU/training, complicated human factors, insufficient anatomical knowledge among users	**6**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing, Design Validation	**3**	**180**	RC: ALARP FA: None
10	**PROSIMA PFRS**	**PROA1, PROP1, PROC2**	Ease-of use by non-specialists	Difficulty for inexperienced users to perform procedure	PE: IFU lacks clarity Haz: Increased complication rate for inexperienced users	**S,C,M**	Extended Surgery (> 30 min)	**9**	Lack of clarity in IFU/training, complicated human factors, insufficient anatomical knowledge among users	**6**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing, Design Validation	**3**	**162**	RC: ALARP FA: None
11	**PROSIMA PFRS**	**PROA1, PROP1, PROC2**	Ease-of use by non-specialists	Difficulty for inexperienced users to perform procedure	PE: IFU lacks clarity Haz: Increased complication rate for inexperienced users	**S,C,M**	Damage to Pelvic Structures	**9**	Lack of clarity in IFU/training, complicated human factors, insufficient anatomical knowledge among users	**6**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing, Design Validation	**3**	**162**	RC: ALARP FA: None
12	**VSD/Balloon Assembly**	**P21026, P21024**	Fills Vaginal Space	Balloon (plug) separates from VSD (During 24 hr period)	PE: Balloon applies pressure to VSD anchor sutures Haz: Sutures tear	**S,C,M**	Pain	**10**	Geometry of plug/reservoir, Material Selection (Surface Finish), Incorrect Force Specification	**5**	T/E	Performance Testing	**3**	**150**	RC: ALARP FA: None
13	**PROSIMA PFRS**	**PROA1, PROP1, PROC2**	Ease-of use by non-specialists	Difficulty for inexperienced users to perform procedure	PE: IFU lacks clarity, Increased complication rate for inexperienced users, Mesh vaginal erosion Haz: None Identified	**S,C,M**	N/A	**7**	Lack of clarity in IFU/training, complicated human factors, insufficient anatomical knowledge among users	**6**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing, Design Validation	**3**	**126**	RC: ALARP FA: None
14	**VSD/Balloon Assembly**	**P21026, P21024**	Fills Vaginal Space	Balloon Bursts	PE: Balloon fragments remain in patient Haz: Fragments remain greater than 24 hrs	**S,M**	Tissue Reaction	**10**	Material selection, Incorrect volume specification	**4**	T/E	Performance Testing, Biocompatibility Assessment	**3**	**120**	RC: ALARP FA: None
15	**VSD/Balloon Assembly**	**P21026, P21024**	Support Mesh in target tissue	VSD/Balloon apply excessive pressure to suture line	PE: Incision does not heal properly Haz: Blood flow to incision restricted	**S**	Tissue Necrosis	**10**	Material Selection, Geometry, Balloon Volume	**4**	T/E	Design Validation, Dr. Carey's Clinical Study (VSD component)	**3**	**120**	RC: ALARP FA: None
16	**VSD/Balloon Assembly**	**P21026, P21024**	Fills Vaginal Space	Balloon (plug) separates from VSD (after 24 hr period)	PE: Balloon applies pressure to VSD anchor sutures Haz: Sutures tear, VSD expelled, loss of support	**S,C,M**	Recurrence	**10**	Geometry of plug/reservoir, Material Selection (Surface Finish), Incorrect Force Specification	**4**	T/E	Performance Testing	**3**	**120**	RC: ALARP FA: None
17	**VSD/Balloon Assembly**	**P21026, P21024**	Support Mesh in target tissue	VSD/Balloon apply excessive pressure to suture line	PE: Incision does not heal properly Haz: Increased bacterial build-up at incision site	**S**	Infection	**10**	Material Selection, Geometry, Balloon Volume	**4**	T/E	Design Validation, Dr. Carey's Clinical Study (VSD component)	**3**	**120**	RC: ALARP FA: None
18	**VSD/Balloon Assembly**	**P21026, P21024**	Support Mesh in target tissue	VSD/Balloon occlude fluid removal, airflow at incision site	PE: Incision does not heal properly Haz: Increased bacterial build-up at incision site	**S**	Infection	**10**	Material Selection, Geometry, Balloon Volume	**4**	T/E	Design Validation, Dr. Carey's Clinical Study (VSD component)	**3**	**120**	RC: ALARP FA: None
19	**VSD**	**P21026**	Balloon Carrier	VSD/Balloon adhere	PE: Balloon cannot be removed from VSD Haz: Balloon not rated as implant (Biocomp)	**S**	Tissue Reaction	**10**	VSD Material Selection, Surface texture, tolerance Stack	**4**	T/E	Stability Testing	**3**	**120**	RC: ALARP FA: None
20	**VSD**	**P21026**	Minimize bacterial growth	VSD applies excessive pressure to suture line	PE: Incision does not heal properly Haz: Blood flow to incision restricted	**S**	Tissue Necrosis	**10**	Material Selection, Geometry, Balloon Volume	**4**	T/E	Design Validation, Dr. Carey's Clinical Study (VSD component)	**3**	**120**	RC: ALARP FA: None
21	**VSD**	**P21026**	Vaginal Stabilization (Length and Width)	VSD is too rigid	PE: VSD does not conform to vaginal cavity Haz: Excessive vaginal pressure	**S**	Tissue Necrosis	**10**	Geometry, Material Selection, Incorrect Stiffness spec.	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing, Dr. Carey's Study	**3**	**120**	RC: ALARP FA: None
22	**VSD**	**P21026**	Vaginal Stabilization (Length and Width)	Unintentional expulsion of VSD from vagina (< 2 weeks)	PE: Loss of mesh support during tissue in growth period Haz: Loss of Mesh approximation	**S,C,M**	Recurrence	**10**	Geometry, Material Properties (surface texture & density), Number/Location of stays, Compatibility w/balloon	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**3**	**120**	RC: ALARP FA: None
23	**VSD**	**P21026**	Provide for Ease of placement in vaginal cavity	VSD does not easily fit through vaginal opening	PE: VSD cannot be inserted by user, User only packs vaginal cavity Haz: Loss of Mesh approximation	**S**	Recurrence	**10**	Surface texture, Material Selection, Flexibility, Shape, Grips (features)	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**3**	**120**	RC: ALARP FA: None
24	**VSD**	**P21026**	Conform to Vaginal Shape	VSD does not maintain vaginal shape (does not have trapezoidal shape, does not have angular offset, flexibility)	PE: Vagina shape distorts Haz: Loss of Vaginal Stabilization	**S**	Recurrence	**10**	VSD Shape (size, thickness)	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Dr. Carey's Study	**3**	**120**	RC: ALARP FA: None

Design FMEA: PROSIMA

Doc # 0000330

Line ID	Component	Dwg # w/rev	Function	Potential Failure Mode	Potential Effect (PE)& Hazard (Haz)	Fault Class	Harm	Severity	Potential Cause	Occurrence	Basis	Control Method	Detection	RPN	Risk Category/ Further Action (after Options Analysis)
25	VSD	P21026	Conform to Vaginal Shape	VSD does not maintain vaginal shape (does not have trapezoidal shape, does not have angular offset, flexibility)	PE: Vagina shape distorts Haz: Dyspareunia	S	Pain	10	VSD Shape (size, thickness)	4	T/E	Cadaveric User Evaluations, Usability Studies, Dr. Carey's Study	3	120	RC: ALARP FA: None
26	VSD	P21026	Balloon Carrier	VSD impedes visualization of Balloon	PE: Cannot determine balloon inflation status (visual/tactile) - balloon not inflated Haz: Loss of Vaginal Stabilization	S	Recurrence	10	VSD Shape (size, thickness)	4	T/E	Cadaveric User Evaluations, Usability Studies	3	120	RC: ALARP FA: None
27	VSD	P21026	Vaginal Stabilization (Length and Width)	VSD is too flexible	PE: Loss of mesh support during tissue in growth period Haz: Loss of Mesh approximation	S	Recurrence	10	Geometry, Material Selection, Incorrect Stiffness spec.	4	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing, Dr. Carey's Study	3	120	RC: ALARP FA: None
28	VSD	P21026	Approximate Mesh during tissue In-growth	Mesh curls, twists, bunches, sags (looses flatness)	PE: Impede tissue in-growth through mesh Haz: Tissue does not encapsulate mesh	S,C,M	Pain	10	Geometry, Material Selection (stiffness)	4	T/E	Cadaveric User Evaluations, Usability Studies, Dr. Carey's Study	3	120	RC: ALARP FA: None
29	VSD	P21026	Prevention of Post-operative Adhesions	Tissue to Tissue adhesions form	PE: Loss of VSD freedom of motion Haz: Tissue tearing	S	Pain	10	Geometry/Shape of VSD, Surface Finish	4	T/E	Material Specifications, Performance Testing, Dr. Carey's Study	3	120	RC: ALARP FA: None
30	VSD	P21026	Prevention of Post-operative Adhesions	Tissue to Tissue adhesions form	PE: Excessive difficulty during VSD removal Haz: Tissue tearing	S	Pain	10	Geometry/Shape of VSD, Surface Finish	4	T/E	Material Specifications, Performance Testing, Dr. Carey's Study	3	120	RC: ALARP FA: None
31	VSD	P21026	Vaginal Stabilization (Length and Width)	Unintentional expulsion of VSD from vagina (< 2 weeks)	PE: (Anterior to Posterior) vaginal separation lost Haz: Increased chance of Adhesion (post-op)	S,C,M	Pain	10	Geometry, Material Properties (surface texture & density), Number/Location of stays, Compatibility w/balloon	4	T/E	Cadaveric User Evaluations, Usability Studies	3	120	RC: ALARP FA: None
32	VSD	P21026	Prevention of Post-operative Adhesions	VSD adheres to surrounding vaginal tissue	PE: Loss of VSD freedom of motion Haz: Tissue tearing	S	Pain	10	Material Selection, Shape (rough, protruding features)	4	T/E	Material Specifications, Performance Testing	3	120	RC: ALARP FA: None
33	VSD	P21026	Approximate Mesh during tissue In-growth	Mesh loosely contacts tissue	PE: Impede tissue in-growth through mesh, Loss of Mesh approximation Haz: Redundant Vagina	S,C,M	Secondary Procedure (corrective)	10	Geometry, Material Selection (stiffness)	4	T/E	Cadaveric User Evaluations, Usability Studies, Dr. Carey's Study	3	120	RC: ALARP FA: None
34	VSD	P21026	Vaginal Stabilization (Length and Width)	Unintentional expulsion of VSD from vagina (> 2 weeks)	PE: Vaginal shape (length) is distorted Haz: Dyspareunia	S,C,M	Pain	10	Geometry, Material Properties (surface texture & density), Number/Location of stays, Compatibility w/balloon	4	T/E	Cadaveric User Evaluations, Usability Studies	3	120	RC: ALARP FA: None
35	VSD	P21026	Vaginal Stabilization (Length and Width)	Unintentional expulsion of VSD from vagina (< 2 weeks)	PE: (Anterior to Posterior) vaginal separation lost Haz: Increased chance of Adhesion (post-op)	S,C,M	Infection	10	Geometry, Material Properties (surface texture & density), Number/Location of stays, Compatibility w/balloon	4	T/E	Cadaveric User Evaluations, Usability Studies	3	120	RC: ALARP FA: None
36	VSD	P21026	Minimize bacterial growth	VSD applies excessive pressure to suture line	PE: Incision does not heal properly Haz: Increased bacterial build-up at incision site	S	Infection	10	Material Selection, Geometry, Balloon Volume	4	T/E	Design Validation, Dr. Carey's Clinical Study (VSD component)	3	120	RC: ALARP FA: None
37	VSD	P21026	Minimize bacterial growth	VSD design (shape, size, texture) that promotes bacterial growth	PE: Excessive bacterial colonization Haz: Bacterial growth	S	Infection	10	VSD Shape (corners, crevices, voids), Material Selection	4	T/E	Cadaveric User Evaluations, Usability Studies	3	120	RC: ALARP FA: None
38	VSD	P21026	Minimize bacterial growth	VSD design (shape, size, texture) that promotes bacterial growth	PE: Excessive vaginal discharge Haz: Bacterial growth	S	Infection	10	VSD Shape (corners, crevices, voids), Material Selection	4	T/E	Cadaveric User Evaluations, Usability Studies	3	120	RC: ALARP FA: None
39	VSD	P21026	Balloon Carrier	VSD does not release balloon (as intended)	PE: Balloon remains for duration of VSD support (3-4 weeks) Haz: Not rated as implant (Biocomp)	S	Infection	10	VSD too soft/flexible, Surface texture	4	T/E	Stack Cadaveric User Evaluations, Usability Studies	3	120	RC: ALARP FA: None
40	VSD	P21026	Minimize bacterial growth	VSD occludes fluid removal, airflow at incision site	PE: Incision does not heal properly Haz: Increased bacterial build-up at incision site	S	Infection	10	Material Selection, Geometry, Balloon Volume	4	T/E	Design Validation, Dr. Carey's Clinical Study (VSD component)	3	120	RC: ALARP FA: None

Design FMEA: PROSIMA

Doc # 0000330

Line ID	Component	Dwg # w/rev	Function	Potential Failure Mode	Potential Effect (PE)& Hazard (Haz)	Fault Class	Harm	Severity	Potential Cause	Occurrence	Basis	Control Method	Detection	RPN	Risk Category/ Further Action (after Options Analysis)
41	VSD	P21026	Balloon Carrier	VSD does not release balloon (as intended)	PE: Balloon remains for duration of VSD support (3-4 weeks) Haz: Excessive pressure on bladder	S	Impaired Voiding	10	VSD too soft/flexible, Surface texture	4	T/E	Cadaveric User Evaluations, Usability Studies	3	120	RC: ALARP FA: None
42	VSD	P21026	Vaginal Stabilization (Length and Width)	VSD is too long	PE: Excessive Vaginal Expansion (medial), Excessive Vaginal Pressure, Discomfort Haz: None Identified	S	N/A	8	Incorrect Population data, Geometry	5	T/E	Cadaveric User Evaluations, Usability Studies, Dr. Carey's Study	3	120	RC: ALARP FA: None
43	Syringe	P21028	Indicate balloon inflation status	Does not provide correct feedback for inflation	PE: Method is not adequate for determining balloon inflation Haz: Excessive balloon inflation/excessive balloon pressure	C,M	Pain	10	Syringe Selection, Method Selection - not reliable (Ethicon)	4	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing	3	120	RC: ALARP FA: None
44	PROSIMA PFRS	PROA1, PROP1, PROC2	Correct pelvic organ prolapse	Procedure does not provide proper support for POP defects (posterior, anterior, anterior/apical)	PE: Minimal anchoring of mesh in target tissue Haz: Intended prolapse repair is inadequate	S	Recurrence	10	Equivalence of "Inventor's" procedure to final MINT procedure (use of Inventor's clinical results), Limited Clinical Outcome data (post-surgery time), Incorrect Mesh Selection, Lack of Clinical evidence supporting apical outcomes	4	T/E	Dr. Carey's Clinical Study	3	120	RC: ALARP FA: None
45	Posterior Inserter	P21021	Interface with needle holder	Inserter slips off needle holder (during placement)	PE: Enlarge tissue tunnels Haz: Mesh is placed in wrong location	S,C,M	Recurrence	10	Geometry (Inserter & needle holder), Material Selection (surface finish)	4	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing	3	120	RC: ALARP FA: None
46	Mesh Carrier	P21035	Protects mesh during handling/transfer	Mesh Carrier sticks to tray retainer	PE: Mesh carrier falls outside of the sterile field Haz: Mesh is contaminated	S,M	Tissue Reaction	10	Static force between film and thermo-formed tray lid	4	T/E	Packaging Transit Testing	3	120	RC: ALARP FA: None
47	Balloon	P21024	Removable from patient (independent of VSD)	Balloon does not separate from VSD	PE: Balloon remains in patient for duration of VSD implantation Haz: Balloon may not be biocompatible. for implant duration	S,C	Tissue Reaction	10	Geometry, Material Selection, Tolerance Stack	4	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing, Biocompatibility Assessment	3	120	RC: ALARP FA: None
48	Anterior/Posterior Inserter	P21021, P21020	Detachable from mesh	Mesh snags/stuck on inserter	PE: Inserter displaces mesh implant (not detected) Haz: Mesh does not provide	S	Recurrence	10	Geometry, Surface Finish (slippery/tacky)	4	T/E	Cadaveric User Evaluations, Usability Studies	3	120	RC: ALARP FA: None
49	Anterior Inserter	P21020	Deliver mesh to tissue tunnels	Inserter length too short (misses target tissue)	PE: Mesh improperly positioned Haz: Reduction in apical support	S	Recurrence	10	Geometry, Population data	4	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing	3	120	RC: ALARP FA: None
50	VSD	P21026	Balloon Carrier	Balloon inadvertently detaches from VSD	PE: Balloon is expelled from vaginal cavity (<1 Day) Haz: Redundant vagina	S,C	Secondary Procedure (corrective)	9	VSD reservoir lip tears, Reservoir too large, stack-up (interference)	4	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing	3	108	RC: ALARP FA: None
51	VSD	P21026	Balloon Carrier	VSD impedes visualization of Balloon	PE: Cannot determine balloon inflation status (visual/tactile) - balloon not inflated Haz: Redundant Vagina	S	Secondary Procedure (corrective)	9	VSD Shape (size, thickness), Material Selection	4	T/E	Cadaveric User Evaluations, Usability Studies	3	108	RC: ALARP FA: None
52	Posterior Inserter	P21021	Deliver mesh to tissue tunnels	Inserter length too long	PE: Inserter elongates tissue tunnel Haz: Inserter is placed too deep	S,M	Damage to Pelvic Structures	9	Geometry, Population data	4	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing, Design Validation	3	108	RC: ALARP FA: None
53	Posterior Inserter	P21021	Interface with needle holder	Inserter slips off needle holder (during placement)	PE: Enlarge tissue tunnels Haz: Inserter is placed too deep	S,C,M	Damage to Pelvic Structures	9	Geometry (Inserter & needle holder), Material Selection (surface finish)	4	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing, Design Validation	3	108	RC: ALARP FA: None
54	Cap	P21024	Prevent balloon deflation due to valve leakage	Cap does not complete seal	PE: Balloon deflates, loss of mesh approximation during initial 24 hr period. Haz: Redundant Vagina	S	Secondary Procedure (corrective)	9	Geometry, Attachment method	4	T/E	Performance Testing	3	108	RC: ALARP FA: None

Design FMEA: PROSIMA

Doc # 0000330

Line ID	Component	Dwg # w/rev	Function	Potential Failure Mode	Potential Effect (PE)& Hazard (Haz)	Fault Class	Harm	Severity	Potential Cause	Occurrence	Basis	Control Method	Detection	RPN	Risk Category/ Further Action (after Options Analysis)
55	**Cap**	**P21024**	Prevent balloon deflation due to valve leakage	Cap snaps off of assembly	PE: Balloon deflates, loss of mesh approximation during initial 24 hr period. Haz: Redundant Vagina	**S**	Secondary Procedure (corrective)	**9**	Geometry, Attachment method	**4**	T/E	Performance Testing	**3**	**108**	RC: ALARP FA: None
56	**Balloon**	**P21024**	Inflatable/deflatable (adjustable post-op)	Balloon detaches from plug (post procedure)	PE: Balloon deflates, loss of mesh approximation during initial 24 hr period. Haz: Redundant Vagina	**S**	Secondary Procedure (corrective)	**9**	Geometry, Material Selection, Underestimated pull-force & Balloon weld-strength spec.	**4**	T/E	Performance Testing	**3**	**108**	RC: ALARP FA: None
57	**Balloon**	**P21024**	Maintain Volume (24 hrs)	Balloon Leaks	PE: Balloon deflates, loss of mesh approximation during initial 24 hr period. Haz: Redundant Vagina	**S**	Secondary Procedure (corrective)	**9**	Excessive void specification, material selection (perm), Specified Bond Strength, Attachment method	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing	**3**	**108**	RC: ALARP FA: None
58	**Balloon**	**P21024**	Maintain Volume (24 hrs)	Cap does not seat properly	PE: Balloon deflates, loss of mesh approximation during initial 24 hr period. Haz: Redundant Vagina	**S**	Secondary Procedure (corrective)	**9**	Geometry, Attachment method, Syringe type (lure/non-lure)	**4**	T/E	Performance Testing, Design Validation	**3**	**108**	RC: ALARP FA: None
59	**Balloon**	**P21024**	Inflatable/deflatable (adjustable post-op)	Inflation Line detaches from plug (post procedure)	PE: Balloon deflates, loss of mesh approximation during initial 24 hr period. Haz: Redundant Vagina	**S**	Secondary Procedure (corrective)	**9**	Geometry, Material Selection, Underestimated Pull-Force, Tubing mis-sized	**4**	T/E	Performance Testing	**3**	**108**	RC: ALARP FA: None
60	**Balloon**	**P21024**	Maintain Volume (24 hrs)	Inflation Line Leaks (Valve & Interfaces)	PE: Balloon rapidly deflates, loss of mesh approximation during initial 24 hr period. Haz: Redundant Vagina	**S**	Secondary Procedure (corrective)	**9**	Material Selection, Geometry, Stability, Tolerance Stack	**4**	T/E	Performance Testing	**3**	**108**	RC: ALARP FA: None
61	**Balloon**	**P21024**	Removable from patient (independent of VSD)	Balloon does not separate from VSD	PE: Balloon remains in patient for duration of VSD implantation Haz: Excessive force applied to vaginal cavity (extended duration)	**S,C**	Impaired Voiding	**9**	Geometry, Material Selection	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing	**3**	**108**	RC: ALARP FA: None
62	**Anterior/Posterior Inserter**	**P21021, P21020**	Deliver mesh to tissue tunnels	Inserter too flexible	PE: Control of inserter is reduced, cannot locate mesh at target site Haz: Inadequate mesh support at prolapse site	**S**	Recurrence	**9**	Geometry, Material Selection	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**3**	**108**	RC: ALARP FA: None
63	**Anterior Inserter**	**P21020**	Deliver mesh to tissue tunnels	Inserter length too long	PE: Control of inserter is reduced Haz: Inserter is driven further into target tissue than intended	**S**	Damage to Pelvic Structures	**9**	Geometry, Population data	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**3**	**108**	RC: ALARP FA: None
64	**Anterior Inserter**	**P21020**	Deliver mesh to tissue tunnels	Inserter has incorrect curvature	PE: Inserter elongates tissue tunnel Haz: Inserter is placed too deep	**C**	Damage to Pelvic Structures	**9**	Geometry, Population data	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing, Design Validation	**3**	**108**	RC: ALARP FA: None
65	**VSD/Balloon Assembly**	**P21026, P21024**	Fills Vaginal Space	Balloon does not fill vaginal cavity	PE: Vaginal shape (length) is distorted, Shortened Vagina, Discomfort (during intercourse) Haz: None Identified	**S**	N/A	**6**	Incorrect Patient Population data, Geometry, Material Selection	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**4**	**96**	RC: BA FA: None
67	**Mesh Carrier**	**P21035**	Protects mesh during handling/transfer	Mesh cannot be removed from carrier	PE: Mesh carrier & mesh are discarded, new kit opened Haz: None Identified	**S,M**	N/A	**8**	Mesh Carrier sealing, geometry, material selection	**4**	T/E	Performance Testing, Usability Studies	**3**	**96**	RC: ALARP FA: None
68	**Mesh Carrier**	**P21035**	Protects mesh during handling/transfer	Mesh Carrier sticks to tray retainer	PE: Mesh carrier falls outside of the sterile field, mesh discarded, new kit opened Haz: None Identified	**S,M**	N/A	**8**	Static force between film and thermo-formed tray lid	**4**	T/E	Pilot Build Mesh Sampling memo	**3**	**96**	RC: ALARP FA: None
69	**VSD**	**P21026**	Approximate Mesh during tissue In-growth	Mesh loosely contacts tissue	PE: Impede tissue in-growth through mesh, Loss of Mesh approximation, Mesh vaginal erosion Haz: None Identified	**S,C,M**	N/A	**7**	Geometry, Material Selection (stiffness)	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Dr. Carey's Study	**3**	**84**	RC: ALARP FA: None
70	**VSD**	**P21026**	Vaginal Stabilization (Length and Width)	Unintentional expulsion of VSD from vagina (< 2 weeks)	PE: Loss of mesh support during tissue in growth period, Loss of Mesh approximation, Mesh vaginal erosion Haz: None Identified	**S,C,M**	N/A	**7**	Geometry, Material Properties (surface texture & density), Number/Location of stays, Compatibility w/balloon	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Dr. Carey's Study	**3**	**84**	RC: ALARP FA: None
71	**VSD**	**P21026**	Vaginal Stabilization (Length and Width)	VSD is too flexible	PE: Loss of mesh support during tissue in growth period, Loss of Mesh approximation, Mesh vaginal erosion Haz: None Identified	**S**	N/A	**7**	Geometry, Material Selection, Incorrect Stiffness spec.	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Dr. Carey's Study	**3**	**84**	RC: ALARP FA: None

Design FMEA: PROSIMA

Doc # 0000330

Line ID	Component	Dwg # w/rev	Function	Potential Failure Mode	Potential Effect (PE)& Hazard (Haz)	Fault Class	Harm	Severity	Potential Cause	Occurrence	Basis	Control Method	Detection	RPN	Risk Category/ Further Action (after Options Analysis)
72	**Mesh Carrier**	**P21035**	Protects mesh during handling/transfer	Mesh cannot be removed from carrier	PE: Mesh carrier must be cut away from mesh, Mesh damaged during removal Haz: None Identified	**S,M**	N/A	**7**	Mesh Carrier sealing, geometry, material selection	**4**	T/E	Performance Testing, Usability Studies, Design Validation	**3**	**84**	RC: BA FA: None

Design FMEA: PROSIMA

Doc # 0000330

Line ID	Component	Dwg # w/rev	Function	Potential Failure Mode	Potential Effect (PE)& Hazard (Haz)	Fault Class	Harm	Severity	Potential Cause	Occurrence	Basis	Control Method	Detection	RPN	Risk Category/ Further Action (after Options Analysis)
73	**VSD/Balloon Assembly**	**P21026, P21024**	Fills Vaginal Space	Balloon does not fill vaginal cavity	PE: Inadequate approximation of mesh to tissue, Non-optimal tissue in-growth Haz: None Identified	**S**	N/A	**2**	Incorrect Patient Population data, Geometry, Material Selection	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**10**	**80**	RC: BA FA: None
74	**VSD**	**P21026**	Provide for Ease of placement in vaginal cavity	VSD does not fit through vaginal opening	PE: VSD cannot be inserted by user, User solely packs with gauze Haz: Loss of mesh approximation	**S**	Recurrence	**10**	Surface texture, Material Selection, Flexibility, Shape, Grips (features)	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Dr. Carey's Study	**2**	**80**	RC: ALARP FA: None
75	**Mesh Carrier**	**P21035**	Protects mesh during handling/transfer	Mesh Carrier contaminates mesh	PE: Mesh is non-biocompatible (for implantation) Haz: Non-biocompatible material implanted in patient	**S,M**	Tissue Reaction	**10**	Material selection, geometry	**4**	T/E	Biocompatibility Risk Assessment	**2**	**80**	RC: ALARP FA: None
76	**Mesh Carrier**	**P21035**	Protects mesh during handling/transfer	Mesh cannot be removed from carrier	PE: Mesh carrier must be cut away from mesh Haz: Mesh damaged during removal	**S,M**	Recurrence	**10**	Mesh Carrier sealing, geometry, material selection	**4**	T/E	Performance Testing, Usability Studies	**2**	**80**	RC: ALARP FA: None
77	**Mesh Carrier**	**P21035**	Protects mesh during handling/transfer	Mesh Carrier sticks to tray retainer	PE: Mesh carrier falls outside of the sterile field Haz: Mesh is contaminated	**S,M**	Infection	**10**	Static force between film and thermo-formed tray lid	**4**	T/E	Pilot Build Mesh Sampling memo	**2**	**80**	RC: ALARP FA: None
78	**Balloon**	**P21024**	Maintain Volume (24 hrs)	Cap tether breaks	PE: Cap falls in vaginal cavity Haz: Unintended Implant	**S**	Tissue Reaction	**10**	Geometry, Attachment method	**4**	T/E	Performance Testing, Design Validation, Biocompatibility Assessment	**2**	**80**	RC: ALARP FA: None
79	**VSD**	**P21026**	Provide for Ease of placement in vaginal cavity	Excessive force is required to fold VSD	PE: VSD slips out of surgeons hands, Device falls outside of sterile field and is no longer usable. Haz: Loss of Vaginal Support	**C**	Recurrence	**10**	Surface texture, Material Selection, Flexibility, Geometry	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing, Design Validation	**2**	**80**	RC: ALARP FA: None
80	**VSD**	**P21026**	Approximate Mesh during tissue In-growth	Mesh curls, twists, bunches, sags (looses flatness)	PE: Impede tissue in-growth through mesh, non-optimal tissue in-growth Haz: None Identified	**S,C,M**	N/A	**6**	Geometry, Material Selection (stiffness)	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**3**	**72**	RC: ALARP FA: None
81	**VSD**	**P21026**	Vaginal Stabilization (Length and Width)	Unintentional expulsion of VSD from vagina (< 2 weeks)	PE: Vaginal shape (length) is distorted, Shortened Vagina, Discomfort (during intercourse) Haz: None Identified	**S,C,M**	N/A	**6**	Geometry, Material Properties (surface texture & density), Number/Location of stays, Compatibility w/balloon	**4**	T/E	Dr. Carey's Clinical Study	**3**	**72**	RC: BA FA: None
82	**VSD**	**P21026**	Vaginal Stabilization (Length and Width)	Unintentional expulsion of VSD from vagina (< 2 weeks)	PE: (Anterior to Posterior) vaginal separation lost, Increased chance of Adhesion (post-op), Discomfort (during intercourse) Haz: None Identified	**S,C,M**	N/A	**6**	Geometry, Material Properties (surface texture & density), Number/Location of stays, Compatibility w/balloon	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Dr. Carey's Clinical Study	**3**	**72**	RC: BA FA: None
83	**VSD**	**P21026**	Vaginal Stabilization (Length and Width)	Unintentional expulsion of VSD from vagina (> 2 weeks)	PE: Vaginal shape (length) is distorted, Shortened Vagina, Discomfort (during intercourse) Haz: None Identified	**S,C,M**	N/A	**6**	Geometry, Material Properties (surface texture & density), Number/Location of stays, Compatibility w/balloon	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**3**	**72**	RC: BA FA: None
84	**VSD**	**P21026**	Vaginal Stabilization (Length and Width)	Unintentional expulsion of VSD from vagina (> 2 weeks)	PE: (Anterior to Posterior) vaginal separation lost, Increased chance of Adhesion (post-op), Discomfort (during intercourse) Haz: None Identified	**S,C,M**	N/A	**6**	Geometry, Material Properties (surface texture & density), Number/Location of stays, Compatibility w/balloon	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Dr. Carey's Clinical Study	**3**	**72**	RC: BA FA: None
85	**VSD**	**P21026**	Prevention of Post-operative Adhesions	VSD adheres to surrounding vaginal tissue	PE: Loss of VSD freedom of motion, Tissue tearing, Discomfort Haz: None Identified	**S**	N/A	**6**	Material Selection, Shape (rough, protruding features)	**4**	T/E	Material Specifications, Cadaveric Testing	**3**	**72**	RC: BA FA: None
86	**VSD**	**P21026**	Conform to Vaginal Shape	VSD does not maintain vaginal shape (does not have trapezoidal shape, does not have angular offset, flexibility)	PE: Vagina shape distorts, Shortened Vagina, Discomfort (during intercourse) Haz: None Identified	**S**	N/A	**6**	VSD Shape (size, thickness), Material Selection	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Dr. Carey's Study	**3**	**72**	RC: BA FA: None
87	**VSD**	**P21026**	Vaginal Stabilization (Length and Width)	VSD is too flexible	PE: Vaginal shape (length) is distorted, Shortened Vagina, Discomfort (during intercourse) Haz: None Identified	**S**	N/A	**6**	Geometry, Material Selection, Incorrect Stiffness spec.	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing, Dr. Carey's Study	**3**	**72**	RC: BA FA: None

Design FMEA: PROSIMA

Doc # 0000330

Line ID	Component	Dwg # w/rev	Function	Potential Failure Mode	Potential Effect (PE)& Hazard (Haz)	Fault Class	Harm	Severity	Potential Cause	Occurrence	Basis	Control Method	Detection	RPN	Risk Category/ Further Action (after Options Analysis)
88	**VSD**	**P21026**	Vaginal Stabilization (Length and Width)	VSD is too rigid	PE: VSD does not conform to vaginal cavity, Excessive vaginal pressure, Discomfort Haz: None Identified	**S**	N/A	**6**	Geometry, Material Selection, Incorrect Stiffness spec.	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing, Dr. Carey's Study	**3**	**72**	RC: BA FA: None

Design FMEA: PROSIMA

Doc # 0000330

Line ID	Component	Dwg # w/rev	Function	Potential Failure Mode	Potential Effect (PE)& Hazard (Haz)	Fault Class	Harm	Severity	Potential Cause	Occurrence	Basis	Control Method	Detection	RPN	Risk Category/ Further Action (after Options Analysis)
89	**VSD**	**P21026**	Vaginal Stabilization (Length and Width)	VSD is too Short	PE: Vaginal shape (length) is distorted, Shortened Vagina, Discomfort (during intercourse) Haz: None Identified	**S**	N/A	**6**	Incorrect Population data, Geometry	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing, Dr. Carey's Study	**3**	**72**	RC: BA FA: None
90	**Anterior/Posterior Inserter**	**P21021, P21020**	Atraumatic	Inserter causes tissue trauma	PE: Additional tissue damage to target tissue, Tissue Trauma Haz: None Identified	**S**	N/A	**6**	Geometry, Surface Finish, Sharpness	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**3**	**72**	RC: BA FA: None
91	**VSD/Balloon Assembly**	**P21026, P21024**	Fills Vaginal Space	Balloon Bursts	PE: Excessive pressure applied to suture line, Suture line ruptures, Patient Discomfort Haz: None Identified	**S,M**	N/A	**5**	Material Selection, Incorrect Volume Specification	**4**	T/E	Performance Testing	**3**	**60**	RC: BA FA: None
92	**VSD/Balloon Assembly**	**P21026, P21024**	Fills Vaginal Space	Balloon separates from VSD (During Insertion)	PE: Balloon no longer usable, user applies standard gauze packing Haz: None Identified	**S,M**	N/A	**5**	Geometry of plug/reservoir, Material Selection (Surface Finish), Incorrect Force Specification	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**3**	**60**	RC: BA FA: None
93	**VSD/Balloon Assembly**	**P21026, P21024**	Fills Vaginal Space	Balloon Tears	PE: Balloon deflates during procedure, Gauze Packing placed (standard of care) Haz: None Identified	**S,M,C**	N/A	**5**	Material Selection, geometry of VSD, location of sutures	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**3**	**60**	RC: BA FA: None
94	**VSD**	**P21026**	Balloon Carrier	Balloon inadvertently detaches from VSD	PE: Balloon is expelled from vaginal cavity (immediately post-procedure), gauze packing is placed in lieu of balloon (current standard of care) Haz: None Identified	**S,M**	N/A	**5**	VSD reservoir lip tears, Reservoir too large, stack-up (interference)	**4**	T/E	Stack Cadaveric User Evaluations, Usability Studies, Performance Testing	**3**	**60**	RC: BA FA: None
95	**VSD**	**P21026**	Balloon Carrier	VSD Damages Balloon	PE: Balloon does not deploy, gauze packing is placed in lieu of balloon (current standard of care) Haz: None Identified	**S**	N/A	**5**	VSD shape, surface texture, pinch points, sharp edges	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Design Validation	**3**	**60**	RC: BA FA: None
96	**VSD**	**P21026**	Balloon Carrier	VSD prevents Balloon inflation	PE: Balloon does not deploy. Gauze Packing is used in place of Balloon Haz: None Identified	**S**	N/A	**5**	VSD shape, surface texture, pinch points, sharp edges	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**3**	**60**	RC: BA FA: None
97	**Posterior Inserter**	**P21021**	Interface with needle holder	Cannot grasp Inserter with needle holder	PE: Provided inserter no longer useful for mesh insertion. User places mesh with standard surgical instrument Haz: None Identified	**S**	N/A	**5**	Geometry (Inserter & needle holder), Material Selection (surface finish), Durability	**4**	T/E	Cadaveric User Evaluations, Performance Testing, Design Validation	**3**	**60**	RC: BA FA: None
98	**Posterior Inserter**	**P21021**	Interface with needle holder	Inserter slips off needle holder (during placement)	PE: Enlarge tissue tunnels, Inserter causes tissue damage Haz: None Identified	**S**	N/A	**5**	Geometry (Inserter & needle holder), Material Selection (surface finish)	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**3**	**60**	RC: BA FA: None
99	**Posterior Inserter**	**P21021**	Interface with needle holder	Needle holder damages inserter	PE: Tab bends rendering Needle Holder non-functional, mesh placed with standard surgical instrument Haz: None Identified	**S,M**	N/A	**5**	Inserter Material Selection, Geometry	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Design Validation	**3**	**60**	RC: BA FA: None
100	**Mesh**	**P21005**	Promote delivery to target site	Welds of Mesh Pockets Tear	PE: Provided inserter no longer useful for mesh insertion. User places mesh with standard surgical instrument	**S**	N/A	**5**	Mesh Material Properties, Inserter Sharpness (shape), Pocket Geometry, Incorrect Force Spec.	**4**	T/E	Performance Testing, Design Validation	**3**	**60**	RC: BA FA: None
101	**Balloon**	**P21024**	Inflatable/deflatable (adjustable post-op)	Balloon detaches from plug (during post-op adjustment)	PE: Balloon deflates, gauze packing is placed in lieu of balloon (current standard of care) Haz: None Identified	**S**	N/A	**5**	Geometry, Material Selection, Underestimated Pull-Force & Balloon weld-strength	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing	**3**	**60**	RC: BA FA: None
102	**Balloon**	**P21024**	Maintain Volume (24 hrs)	Cap tether breaks	PE: Cap falls outside of sterile field, device non-usable, surgeon removes balloon and packs with gauze (current standard of care) Haz: None Identified	**S**	N/A	**5**	Geometry, Attachment method	**4**	T/E	Performance Testing, Design Validation	**3**	**60**	RC: BA FA: None
103	**Balloon**	**P21024**	Inflatable/deflatable (adjustable post-op)	Inflation Line detaches from plug (during post-op adjustment)	PE: Balloon deflates, gauze packing is placed in lieu of balloon (current standard of care) Haz: None Identified	**S**	N/A	**5**	Geometry, Material Selection, Underestimated Pull-Force, Tubing mis-sized	**4**	T/E	Performance Testing	**3**	**60**	RC: BA FA: None
104	**Balloon**	**P21024**	Inflatable/deflatable (adjustable post-op)	Valve detaches from inflation line (during post-op adjustment)	PE: Balloon deflates, gauze packing is placed in lieu of balloon (current standard of care) Haz: None Identified	**S**	N/A	**5**	Geometry, Tolerance Stack, Material Selection, Underestimated Pull-Force, Tubing mis-sized	**4**	T/E	Performance Testing	**3**	**60**	RC: BA FA: None

Design FMEA: PROSIMA

Doc # 0000330

Line ID	Component	Dwg # w/rev	Function	Potential Failure Mode	Potential Effect (PE)& Hazard (Haz)	Fault Class	Harm	Severity	Potential Cause	Occurrence	Basis	Control Method	Detection	RPN	Risk Category/ Further Action (after Options Analysis)
105	**Balloon**	**P21024**	Maintain Volume (24 hrs)	Balloon Leaks	PE: Balloon gradually deflates (remains partially inflated up to 1 Day) Haz: None Identified	**S**	N/A	**3**	Excessive void specification, material selection (perm), Specified Bond Strength, Balloon type	**6**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing	**3**	**54**	RC: BA FA: None
106	**Balloon**	**P21024**	Maintain Volume (24 hrs)	Inflation Line Leaks (Valve & Interfaces)	PE: Balloon gradually deflates (remains partially inflated up to 1 Day) Haz: None Identified	**S**	N/A	**3**	Material Selection, Geometry, Stability	**6**	T/E	Performance Testing	**3**	**54**	RC: BA FA: None
107	**VSD/Balloon Assembly**	**P21026, P21024**	Fills Vaginal Space	Balloon Bursts	PE: Excessive pressure applied to suture line, Suture line ruptures, Bleeding Haz: None Identified	**S,M**	N/A	**6**	Material Selection, Incorrect Volume Specification	**4**	T/E	Performance Testing	**2**	**48**	RC: BA FA: None
108	**VSD**	**P21026**	Balloon Carrier	VSD does not release balloon (as intended)	PE: Balloon remains for duration of VSD support (3-4 weeks), Tube and valve remain attached, Minor discomfort Haz: None Identified	**S**	N/A	**4**	VSD too soft/flexible, Surface texture	**4**	T/E	Tolerance Stack, Cadaveric User Evaluations, Usability Studies, Design Validation	**3**	**48**	RC: BA FA: None
109	**Mesh**	**P21005**	Promote delivery to target site	Difficulty inserting mesh onto inserter	PE: Potential damage to pocket, Mesh inserted with standard surgical accessories. Haz: None Identified	**S**	N/A	**4**	Size of Mesh Pocket, Size of Inserter, Pocket Orientation, Poor Visual Contrast, Mesh Material Selection	**4**	T/E	Stack, Cadaveric User Evaluations, Usability Studies, Performance Testing	**3**	**48**	RC: BA FA: None
110	**Mesh**	**P21005**	Compatible with Inserter	Mesh Pocket tears	PE: Provided inserter no longer useful for mesh insertion. User places mesh with standard surgical instrument Haz: None Identified	**S,M**	N/A	**4**	Mesh Material Properties, Inserter Sharpness (shape), Pocket Geometry, Incorrect Force Spec.	**4**	T/E	Performance Testing, Design Validation	**3**	**48**	RC: BA FA: None
111	**Mesh**	**P21005**	Promote delivery to target site	Mesh Pocket will not fit on inserter	PE: Provided inserter no longer useful for mesh insertion. User places mesh with standard surgical instrument Haz: None Identified	**S**	N/A	**4**	Size of Mesh Pocket, Size of Inserter, Pocket Orientation	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Design Validation	**3**	**48**	RC: BA FA: None
112	**Mesh**	**P21005**	Compatible with Inserter	Mesh Pockets are too shallow (depth)	PE: Provided inserter no longer useful for mesh insertion. User places mesh with standard surgical instrument Haz: None Identified	**S**	N/A	**4**	Inserter Geometry, Weld Locations, Pocket Size	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Design Validation	**3**	**48**	RC: BA FA: None
113	**Balloon**	**P21024**	Removable from patient (independent of VSD)	Balloon is difficult to separate from VSD	PE: VSD is displaced in Vagina, patient discomfort Haz: None Identified	**C**	N/A	**4**	Geometry, Material Selection, Underestimated Pull-Force, Balloon caught on patient, Stability	**4**	T/E	Stack, Cadaveric User Evaluations, Usability Studies, Performance Testing	**3**	**48**	RC: BA FA: None
114	**Anterior/Posterior Inserter**	**P21021, P21020**	Detachable from mesh	Inserter damaged	PE: Provided inserter no longer useful for mesh insertion (opposite side). User places mesh with standard surgical instrument Haz: None Identified	**S,M**	N/A	**4**	Material Selection, Geometry	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing	**3**	**48**	RC: BA FA: None
115	**Balloon**	**P21024**	Maintain Volume (24 hrs)	Cap does not seat properly	PE: Balloon gradually deflates (remains partially inflated up to 1 Day) Haz: None Identified	**S**	N/A	**3**	Geometry, Attachment method	**5**	T/E	Performance Testing, Design Validation	**3**	**45**	RC: BA FA: None
116	**Syringe**	**P21028**	Attachable/detachable to balloon	Syringe cannot mate with valve	PE: Balloon cannot be inflated w/ syringe, gauze packing is placed in lieu of balloon (current standard of care)	**S**	N/A	**5**	Incorrect valve specification, Syringe Selection	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing	**2**	**40**	RC: BA FA: None
117	**Balloon**	**P21024**	Inflatable/deflatable (adjustable post-op)	Syringe & Valve will not connect (inflation)	PE: Balloon cannot be inflated w/ syringe, gauze packing is placed in lieu of balloon (current standard of care) Haz: None Identified	**S**	N/A	**5**	Syringe Selection	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing	**2**	**40**	RC: BA FA: None
118	**Anterior/Posterior Inserter**	**P21021, P21020**	Deliver mesh to tissue tunnels	Inserter too slippery	PE: Difficult to grasp inserter, Device falls outside of sterile field, device no longer usable Haz: None Identified	**S**	N/A	**5**	Surface finish, Geometry	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing, Design Validation	**2**	**40**	RC: BA FA: None
119	**VSD**	**P21026**	Balloon Carrier	VSD distorts	PE: Balloon does not fully deploy (Partially deploys), Balloon does not completely fill cavity Haz: None Identified	**S**	N/A	**3**	VSD too Flexible, Material Selection, loss of suture integrity	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing	**3**	**36**	RC: BA FA: None

Design FMEA: PROSIMA

Doc # 0000330

Line ID	Component	Dwg # w/rev	Function	Potential Failure Mode	Potential Effect (PE)& Hazard (Haz)	Fault Class	Harm	Severity	Potential Cause	Occurrence	Basis	Control Method	Detection	RPN	Risk Category/ Further Action (after Options Analysis)
120	**Mesh**	**P21005**	Promote delivery to target site	Mesh Pockets Tear	PE: Provided inserter no longer useful for mesh insertion. User places mesh with standard surgical instrument Haz: None Identified	**S**	N/A	**3**	Mesh Material Properties, Inserter Sharpness (shape), Pocket Geometry, Incorrect Force Spec.	**4**	T/E	Performance Testing	**3**	**36**	RC: BA FA: None

Design FMEA: PROSIMA

Doc # 0000330

Line ID	Component	Dwg # w/rev	Function	Potential Failure Mode	Potential Effect (PE)& Hazard (Haz)	Fault Class	Harm	Severity	Potential Cause	Occurrence	Basis	Control Method	Detection	RPN	Risk Category/ Further Action (after Options Analysis)
121	**Balloon**	**P21024**	Inflatable/deflatable (adjustable post-op)	Valve plug stuck closed	PE: Balloon cannot be deflated w/ syringe, Balloon punctured to deflate Haz: None Identified	**S,M**	N/A	**3**	Geometry, Materials, Surface Finish	**4**	T/E	Performance Testing	**3**	**36**	RC: BA FA: None
122	**Anterior Inserter**	**P21020**	Deliver mesh to tissue tunnels	Inserter length too long	PE: Inserter is difficult to manipulate (interferes with patient anatomy - thigh/buttocks) Haz: None Identified	**S**	N/A	**3**	Geometry, Population data	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**3**	**36**	RC: BA FA: None
123	**VSD/Balloon Assembly**	**P21026, P21024**	Fills Vaginal Space	Balloon improperly located (via VSD)	PE: Balloon inflation laterally Haz: None Identified	**S**	N/A	**2**	Geometry of plug/reservoir, Material Selection (Surface Finish)	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**4**	**32**	RC: BA FA: None
124	**PROSIMA PFRS**	**PROA1, PROP1, PROC2**	Maintain device functionality	Device is not functional when removed from package	PE: Non-functional device - Packaging failed during transportation Haz: None Identified	**S**	N/A	**8**	Materials not compatible with sterilization method	**4**	T/E	Stability Testing	**6**	**32**	RC: ALARP FA: None
125	**Mesh**	**P21005**	Provide lateral & Apical vaginal support	Incorrect body shapes	PE: Implant excessively large creating bunches and improper support Haz: Loss of Vaginal Support	**S**	Recurrence	**10**	Incorrect patient population data	**1**	D/A	Cadaveric User Evaluations, Dr. Carey's Study, DRM Memo-Mesh Size	**3**	**30**	RC: ALARP FA: None
126	**Mesh**	**P21005**	Provide lateral & Apical vaginal support	Incorrect body shapes	PE: Implant too small causing improper support Haz: Repair with excessive tension	**S,M**	Recurrence	**10**	Incorrect patient population data	**1**	D/A	Cadaveric User Evaluations, Dr. Carey's Study, DRM Memo-Mesh Size	**3**	**30**	RC: ALARP FA: None
127	**VSD/Balloon Assembly**	**P21026, P21024**	Fills Vaginal Space	Balloon separates from VSD (During Insertion)	PE: User repositions balloon in VSD Haz: None Identified	**S,M**	N/A	**2**	Geometry of plug/reservoir, Material Selection (Surface Finish), Incorrect Force Specification	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**3**	**24**	RC: BA FA: None
128	**VSD/Balloon Assembly**	**P21026, P21024**	Fills Vaginal Space	Balloon shifts in VSD	PE: Balloon oriented off axis in vaginal cavity, Non-optimal balloon position Haz: None Identified	**S**	N/A	**2**	Geometry of plug/reservoir, Material Selection (Surface Finish)	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**3**	**24**	RC: BA FA: None
129	**VSD/Balloon Assembly**	**P21026, P21024**	Support Mesh in target tissue	VSD does not provide adequate support	PE: Mesh wrinkle/fold Haz: None Identified	**S**	N/A	**2**	Number of/Location of Suture stays, Geometry of VSD (distort under pressure), Material Selection	**4**	T/E	Dr. Carey's Clinical Study, Design Validation	**3**	**24**	RC: BA FA: None
130	**VSD**	**P21026**	Provide for Ease of placement in vaginal cavity	Excessive force is required to fold VSD	PE: User experiences minor discomfort Haz: None Identified	**S**	N/A	**2**	Surface texture, Material Selection, Flexibility, Geometry	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing	**3**	**24**	RC: BA FA: None
131	**VSD**	**P21026**	Balloon Carrier	VSD does not release balloon (as intended)	PE: User cuts lip to release balloon Haz: None Identified	**S**	N/A	**2**	VSD too soft/flexible, Surface texture	**4**	T/E	Tolerance Stack, Usability Studies, Design Validation	**3**	**24**	RC: BA FA: None
132	**VSD**	**P21026**	Balloon Carrier	VSD prevents Balloon inflation	PE: Balloon does not fully deploy (Partially deploys), Balloon does not completely fill cavity Haz: None Identified	**S**	N/A	**2**	VSD too Flexible, Material Selection	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**3**	**24**	RC: BA FA: None
133	**VSD**	**P21026**	Balloon Carrier	VSD prevents full deflation	PE: Balloon does not fully deflate. User punctures Balloon to deflate. Haz: None Identified	**S**	N/A	**2**	Syringe/Valve selection	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**3**	**24**	RC: BA FA: None
134	**Syringe**	**P21028**	Provide for inflation of balloon	Syringe volume selection too small	PE: User annoyance due to excessive inflation pumps Haz: None Identified	**S**	N/A	**2**	Incorrect Balloon Spec (burst), Std. Syringe availability	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing	**3**	**24**	RC: BA FA: None
135	**Mesh**	**P21005**	Compatible with Inserter	Mesh Pockets are too Narrow	PE: Potential damage to pocket Haz: None Identified	**S**	N/A	**2**	Inserter Geometry, Weld Locations	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing	**3**	**24**	RC: BA FA: None
136	**Balloon**	**P21024**	Inflatable/deflatable (adjustable post-op)	Syringe & Valve will not connect (deflation)	PE: Balloon cannot be deflated w/ syringe, Balloon punctured for deflation Haz: None Identified	**S**	N/A	**3**	Syringe Selection, Valve Selection	**4**	T/E	Stack, Cadaveric User Evaluations, Usability Studies, Performance Testing	**2**	**24**	RC: BA FA: None
137	**Anterior/Posterior Inserter**	**P21021, P21020**	Detachable from mesh	Inserter tears mesh during extraction	PE: Minor mesh damage Haz: None Identified	**S**	N/A	**2**	Sharpness, Material Selection (rigidity), Geometry	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**3**	**24**	RC: BA FA: None

Design FMEA: PROSIMA

Doc # 0000330

Line ID	Component	Dwg # w/rev	Function	Potential Failure Mode	Potential Effect (PE)& Hazard (Haz)	Fault Class	Harm	Severity	Potential Cause	Occurrence	Basis	Control Method	Detection	RPN	Risk Category/ Further Action (after Options Analysis)
138	**Anterior Inserter**	**P21020**	Deliver mesh to tissue tunnels	Inadequate differentiation of left/right use	PE: Left/Right side end used to insert mesh used on opposite side. Greater insertion difficulty, resistance	**S**	N/A	**2**	Inadequate user VOC/Feedback, Etching Method	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Design Validation	**3**	**24**	RC: BA FA: None
139	**Syringe**	**P21028**	Attachable/detachable to balloon	Syringe does not lock on valve	PE: User annoyance, User must hold syringe on valve Haz: None Identified	**S**	N/A	**2**	Incorrect valve specification, Syringe Selection	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Performance Testing	**2**	**16**	RC: BA FA: None
140	**PROSIMA PFRS**	**PROA1, PROP1, PROC2**	Maintain device functionality	Balloon unfolds in kit (during sterilization)	PE: Balloon no longer folded inward, Increased balloon manipulation by user Haz: None	**S**	N/A	**1**	Inadequate air-evacuation technique, Sterilization cycle	**4**		Performance Testing, Design Validation	**4**	**16**	RC: BA FA: None
141	**VSD**	**P21026**	Vaginal Stabilization (Length and Width)	Unintentional expulsion of VSD from vagina (> 2 weeks)	PE: Vagina stabilized, Initial mesh in-growth complete Haz: None Identified	**S,C,M**	N/A	**1**	Geometry, Material Properties (surface texture & density), Number/Location of stays, Compatibility w/balloon	**4**	T/E	Cadaveric User Evaluations, Usability Studies, Dr. Carey's Clinical Study	**3**	**12**	RC: BA FA: None
142	**Posterior Inserter**	**P21021**	Deliver mesh to tissue tunnels	Inserter length too short (misses target tissue)	PE: Use of needle holder to further advance inserter to target site Haz: None Identified	**S**	N/A	**1**	Geometry, Population data	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**3**	**12**	RC: BA FA: None
143	**Balloon**	**P21024**	Maintain Volume (24 hrs)	Cap does not seat properly	PE: Valve fully engaged, Balloon stays inflated Haz: None Identified	**S**	N/A	**1**	Geometry, Attachment method	**4**	T/E	Performance Testing, Design Validation	**3**	**12**	RC: BA FA: None
144	**Balloon**	**P21024**	Inflatable/deflatable (adjustable post-op)	Valve plug stuck open	PE: Cap seals valve from leakage Haz: None Identified	**S**	N/A	**1**	Material Selection, s, Surface Finish	**4**	T/E	Performance Testing	**3**	**12**	RC: BA FA: None
145	**Anterior/Posterior Inserter**	**P21021, P21020**	Deliver mesh to tissue tunnels	Inserter does not fit in tissue tunnel width	PE: Inserter enlarges tissue tunnel Haz: None Identified	**S**	N/A	**1**	Geometry, Surface Finish	**4**	T/E	Cadaveric User Evaluations, Usability Studies	**3**	**12**	RC: BA FA: None
146	**VSD**	**P21026**	Provide for Ease of placement in vaginal cavity	User cannot fold VSD	PE: VSD difficult to insert, Tissue trauma, Bleeding Haz: None Identified	**S**	N/A	**5**	Surface texture, Material Selection, Flexibility, Shape, Grips (features)	**1**	D/A	Cadaveric User Evaluations, Usability Studies, Performance Testing	**2**	**10**	RC: BA FA: None
147	**Mesh**	**P21005**	Promote tissue in-growth (Pockets)	Loss of tissue in growth	PE: Loss of tissue in growth in local mesh pocket area, Mesh body provides adequate support Haz: None Identified	**S**	N/A	**1**	Occluded pore size, Excessively Rigid, Edge Quality, Surface texture, Thickness	**4**	T/E	Minimize Mesh Pocket/Weld size	**2**	**8**	RC: BA FA: None
148	**Mesh**	**P21005**	Promote tissue in-growth (Pockets)	Mesh Pocket Stiffer than mesh body	PE: Deep posterior placement of mesh straps (placement away from functional vaginal area) Haz: None Identified	**S**	N/A	**1**	Occluded pore size, Excessively Rigid, Edge Quality, Surface texture, Thickness	**4**	T/E	Minimize Mesh Pocket/Weld size	**2**	**8**	RC: BA FA: None

Documents Referenced in body of FMEA

Doc Ref	Tiltle/Author	Storage Location
Design Verification Testing	*Completion Report for Protocol for MINT Pelvic Floor Repair (PFR) System (PROSIMA), Version 1/* Amitha Kumar, 3/12/2007 *Report for Design Verification for Human Factors and Performance/* Stephanie Kute, 3/13/2007	eDHF0000121 DR0000064 DVPR0000064
Packaging Performance Testing	Package Performance Testing Completion Report(s)/ Peter Komarnycky	eDHF0000121, CR0000119 Rev A CR0000119 Rev B CR0000119 Rev C CR0000119 Rev D
Stability Testing	*Real-Time Aging Stability Study Protocol: Expiration Date Testing of the MINT (Prosima) Pelvic Floor Repair System* / Amitha Kumar, 11/17/2006 *Accelerated Aging Stability Study Protocol for: MINT (Prosima) Pelvic Floor Repair System* / Amitha Kumar, 11/17/2006 *Stability Study #1467- 6 Month Interim Shelf-Life Report/* Amith Kumar, 2/28/2007 *Stability Study #1467- 14 Month Interim Shelf-Life Report* / Amith Kumar, 4/10/2007	eDHF0000121, PT0000120 (STAB) CR0000120 (STAB) SUBOTH0002228 SUBOTH0002229
Dr. Carey's Clinical Study Summary	Carey Abstract, *Vaginal surgery for pelvic organ prolapse using mesh and a vaginal support device/* Dr. Marcus Carey	eDHF0000121 OTHER0000952
Material Specifications	See General Material Specifications contained in eDHF (Mesh, Inserters, Syringe, VSD, Balloon, Mesh Carrier, Blister Lids, Trays, Boxes, IFUs)	eDHF0000121, MS0000120
Biocompatibility Assessment	*Biocompatibility Risk Assessment: Prosima Pelvic Floor Repair System (MINT)/* Sandy Savidge, 12/27/2006 *Biocompatibility Risk Assessment Update: Prosima Pelvic Floor Repair System (MINT) Implant Carrier/* Sandy Savidge, 1/12/07	eDHF000012, CR0000120 (BIO)
Design Validation	*Design Validation Report, GYNECARE PROSIMA Pelvic Floor Repair System/* Stephanie Kute, 3/16/2007	eDHF0000121 CR0000120 (Dval)
GYNEMESH PS - Risk Assessments	*Device Design Safety Assessment for GYNEMESH PS (GPSL)/* Enilma Miller, 6/6/2002	DHF0956